REMARKS

The application has been amended and is believed to be in condition for allowance.

There are no formal matters outstanding.

Applicants acknowledge with appreciation that claims 7-8, 10-31, 33, 35-37, and 40 have been indicated to be directed to allowable subject matter.

Claim 10 has been amended to include the recitations of base claim 1. Allowance of claim 10 and claims 11-21 depending therefrom is solicted.

Claims 1-6, 9, 32, and 45 stand rejected as anticipated by HODSON et al. 5,347,998.

Claims 38, 39, and 41-44 stand rejected as obvious over HODSON et al. in view of WAKEMAN 3,151,618.

Claims 1 and 45 are believed patentable over HODSON et al. as this reference is not believed to be anticipatory.

Claim 1 recites: "a return controller ... for deactivating said canister to close said opening, wherein, said return controller deactivates said canister when the airflow drops below a certain threshold value." Claim 45 recites: "a return controller closing the inhaler and stopping dispensing medicament responsive to an airflow from the inhaler falling below a set threshold value."

For this feature, there is offered from HODSON et al. a spring or return spring means 99 which is said to control or bias the rocker elements 90 to a position that prevents activation of the canister when inhalation terminates. Reference is made to column 6, lines 25-28 "[t]he rocker element (90) is biased by a spring (99) to its blocking position when patient inspiration is halted."

This column 6 passage pertains to the embodiment of Figure 6, of the type disclosed by Lammond WASS EP 147028 (column 5, lines 42-45). See column 5, beginning at line 42:

"FIG. 6 illustrates a breath actuated pressurized aerosol dispenser of the type disclosed in European Patent No. 147028, but modified for use with the present invention. The lever assembly used to compress the cocking spring has been removed to allow the device to be primed by electromechanical means described hereinafter. The unmodified device is commercially available under the trade name AUTOHALER from Minnesota Mining and Manufacturing Company."

In WASS, the return of the canister after completing delivery of the medicament is not triggered by the patient's inhalation. In the illustrated embodiment, the force on the canister is exerted by the hand of the user. When the user inhales, the canister is free to be depressed because of the user force and because the movement blocking the canister is removed

by the vane. In order to return the canister to the un-depressed state, the user releases the pressure on the canister, whereby it is returned by the internal spring. In the device of WASS, the inhalation only triggers the start of delivery and does not determine the return of the canister. The vane and the movement blocker are thereafter returned to their initial position by a spring or the like.

Similarly, the same function is obtained by the HODSON et al. device, with the difference that the force on the canister is performed by electro-mechanical means (column 5, lines 45-48). See column 6, line 32 through column 7, line 66, disclosing a servo motor or the like primes the canister and exerts a pressure on the canister until a patient inhales, the inhalation moving the movement blocker via the vane and the medicament is delivered.

However, the end of the inhalation does not return the canister to its un-depressed state. Rather, a timer or contacts accomplish this. Only thereafter, the spring 99 is capable of returning the rocker element 90 to its blocking position.

Claim 1 recites: "a return controller … for deactivating said canister to close said opening, wherein, said return controller deactivates said canister when the airflow drops below a certain threshold value." Claim 45 recites: "a return controller closing the inhaler and stopping dispensing

medicament responsive to an airflow from the inhaler falling below a set threshold value." The spring 99 does not deactivate the canister to close the opening, when the airflow drops below a threshold value, or as per claim 45, "closing the inhaler and stopping dispensing medicament responsive to an airflow from the inhaler falling below a set threshold value." The electro-mechanical means moves the canister downwards until electrical signals (contact or timer) reverses the movement of the electro-mechanical means. The rocker element returning spring cannot affect the movement of the canister. Rather, it is the movement of the canister that enables the return of the rocker element to return to its initial position.

Beginning at line 50 of column 5, there is disclosed aerosol container (74) incorporating a mouthpiece (76). The aerosol container (74) feeds hollow valve stem (78) located within a socket (80) in the nozzle block (82). The nozzle block (82) includes a passage way (84) which communicates with the socket (80) and mouthpiece (76) to allow for the medicament release.

Discharge is effected by relative movement between the body of the aerosol canister (74) and the valve stem (78) under the influence of **cocking spring (86)**. This movement is, when the device is not in use, blocked by a breath actuated blocking mechanism comprising vane (88) which is pivotally mounted within

the mouthpiece (76) and a rocker element (90) which supports a catch (92) pivotally mounted thereon at (94).

Figure 8 shows the blocking mechanism in its blocking position where movement of the aerosol canister (74) is prevented by the rocker element (90). Movement of the rocker element (90) is in turn prevented by the catch (92) which has a curved surface (96) engaging the curved surface (98) of the vane (88). A patient inhales through the mouthpiece (76) causes pivotal movement of the vane (88) as shown to displace from a blocking to a nonblocking position which permits pivotal movement of the rocker element (90) and, in turn, movement of the aerosol canister (74) relative to the valve stem (78), **thereby firing the valve and releasing a metered dose of medicament.** Note that there is a release of a metered dose and not a release of a dose as determined by the user's action, i.e., stopping inhalation.

Column 7, line 49 discloses that Figure 9 shows the dispenser (70) in its fired state after the patient has breath actuated the device. As a result of the vane (88) lifting, the catch (92) and rocker element (90) rotate to allow the aerosol canister (74) to move downwards **under the influence of the cocking spring** (86), thereby firing the valve and releasing a dose of medicament. In the course of this action two electrical contacts (146 and 148), one or both of which are compliant, e.g., of brass foil, are brought together to complete an electrical

circuit. This sends a signal to the electronics (110) which then initiates the reset procedure.

It is true that at lines 25-27 of column 6, the reference states that the rocker element (90) is biased by a spring (99) to its blocking position when patient inspiration is halted; however, this does not disclose that recited but only indicates the condition of the device elements in a reset state, after re-priming. See the disclosure concerning Figure 7 generally.

See that Figure 8 is a "ready to use" state whereas Figures 6 and 9 are the discharged state. It is the described with respect to Figure 7 that resets the device from that shown by Figures 6, 9 to that shown by Figure 8.

Referring to Figure 7, the components of the electromechanical priming means are shown, e.g., a d.c. servo motor (104) contained in a housing (106), a lead screw (108), an electronic circuit board (110), a battery (112), two limit switches (114 and 116), a push button switch (118) and a carriage (120). To re-prime the canister, the patient depresses the push button (118) sending a signal to the electronics (110). The electronics (110) then energize the d.c. motor (104) driving the carriage (120) down the lead screw (108).

Referring now to column 7, beginning at line 60, after the reset signal is sent, the servo motor (104) is energized with

the opposite polarity to reverse the rotation of the lead screw (108), thereby causing the carriage (120) to move upwards until the arm (142) contacts the upper limit switch (114). This sends a signal to the electronics (110) to deenergize the servo motor (104), the device being reset with cocking spring 86 reset and the rocker element (90) being biased by a spring (99) to its blocking position as the canister 74 is moved and allowing spring 99 to contract.

Note the passage beginning at line 67 of column 7, wherein is stated that the time between the detection of the valve firing by the closing of contacts (146 and 148) and the initiation of the reset procedure can be dictated by the electronics (i.e., not be termination of the inhalation). "Indeed it is advantageous to introduce a short delay so that the important breath holding period after inhalation of the dose is not interrupted by the sensation of the device resetting." This clearly indicates that the electronics control the closure of the inhaler and not the spring 99.

As the reference fails to disclose this recited feature of the present invention found in the independent claim, the independent claim, as well as the claims depending therefrom, is believed to be allowable. Reconsideration and allowance of all the pending claims are respectfully requested.

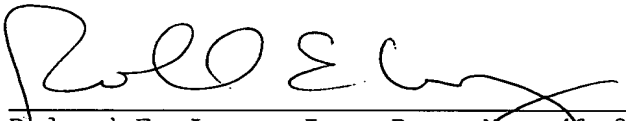
Applicants believe that the present application is in condition for allowance and an early indication of the same is respectfully requested.

Should there be any matters that need to be resolved in the present application; the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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